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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,237	07/17/2003	Peter Robert Baum	2873-USA	4633

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IMMUNEX CORPORATION
LAW DEPARTMENT
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EXAMINER	
HADDAD, MAHER M	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,237	BAUM ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 27 November 2006.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 18 and 20-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 18 and 20-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/27/06 has been entered.

2. Claims 18 and 21-23 are pending are pending and under examination in the instant application.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(e1) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

4. Claims 18 and 20-23 are rejected under 35 U.S.C. 102(e2) as being anticipated by U.S. Patent No. 6,642,360, as is evidenced by Bost et al for the same reasons set forth in the previous Office Action mailed 7/15/05.

5. Claims 18 and 20-23 are rejected under 35 U.S.C. 102(e1) as being anticipated by Pub. No. U.S. 2002/0198147 A1, as is evidenced by Bost et al for the same reasons set forth in the previous Office Action mailed 7/15/05.

Applicant's arguments, filed 11/27/06, have been fully considered, but have not been found convincing.

Applicant's response points to the court in *Noelle v. Lederman* statement that:

> "Therefore, based on our past precedent, **as long as an applicant has disclosed a "fully characterized antigen,"** either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, **the applicant can then claim an antibody by its binding affinity to that described antigen.**" (emphasis added by applicant, 60 USPQ2d 1541, 1508 (CAFC 2004).

Wherein the Headnotes under "Patentability/validity-Specification-Written Description" for *Noelle v. Lederman* case, it states

> **"patent claim directed to any antibody which is capable of binding to particular antigen has sufficient support in written description that discloses "fully characterized" antigens; thus if applicant has disclosed fully characterized antigen, either by structure, formula, chemical name, or physical properties, or by depositing protein in public depository, then applicant can claim antibody by its binding affinity to that described antigen." (Id).**

Further, Applicant's response quotes Enzo court decision:

> "For example, the PTO would find compliance with 112, paragraph I, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature." (*Enzo Biochem v. Gen-Probe. Inc.,* 323 F.3d 956, 970 (Fed. Cir 2002)).

Applicant argues that Noelle did not meet the written description requirement for his claims to antibodies that bound the human sequence was due to the fact that he did not provide the human sequence-he only provided the mouse sequence. If he had provided the human sequence, the written description requirement would have been satisfied ("if Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen." Noelle v. Lederman at 1515). Simply put, if you provide a fully characterized antigen, you've provided written description for antibodies that bind that antigen. It is a situation unique to antibodies-describing the antigen provides written support for antibodies to that antigen.

However, while Applicant's declaration sufficiently described SEQ ID NO: 2 and 4, the declaration is silent with regard to the claimed antibodies. That is the declaration does not provide sufficient support for claims to antibody because the declaration failed to disclose when the claimed antibodies were made. Simply put, had the declaration contemplated the claimed antibodies, then the declaration would have been sufficient to overcome the rejections. The declaration only show that Applicants are in possession of SEQ ID NOs: 2 and 4 prior to 12/3/97 but fails to show that Applicants have the antibody to the antigen. That is the declaration does

not provide support for the claimed antibodies. As in *Noelle v. Lederman* to satisfy the written description the specification should have written support for both the antigen and the antibodies to claim "any antibody which is capable of binding to antigen X." Neither concept alone is sufficient for claims drawn to antibodies to the antigen X. The instant declaration has written support only for the antigen. Establishing that applicants were in possession of the antigen X alone, under written description requirements, is insufficient for claims directed to antibodies to the antigen X.

Applicant contends that since applicants were in possession of a fully characterized antigen prior to the cited art, Application have met the written description requirement for antibodies that bind that antigen. Applicant contends that there is no requirement for actual reduction to practice to satisfy the written description requirement.

The Examiner agrees with Applicant's position only if there is a written support for the antibodies that bind that antigen. However, Applicant declaration fails to provide such written support for the claimed antibodies. Applicant possession of a fully characterized antigen alone cannot be extrapolated to claims to an antibody to the antigen in the absence of written support for the claimed antibodies.

Applicants' interpretation of *Noelle v. Lederman* court decision appears to indicate that a prior art disclosure of an antigen alone, would anticipate claims to antibodies to the antigen. However, this is not the standard. Had the `147 application and `360 patent only disclose the antigen, then an obviousness rejection would have been made, and Applicant's declaration establishing that applicants were in possession of the antigens would be sufficient to overcome the obviousness rejection. However, the `147 application and the `360 patent teach the antibody to the antigen and hence anticipates the claimed invention. A declaration should show as much as the prior art of the `147 application and `360 patent, namely the antibody to the antigen, in order to overcome the anticipatory art.

Applicant contends that the Examiner's position is contradicted by the long-standing policies and practices of the USPTO, which directly reflect Federal Circuit precedent. The Written Description Guidelines provide Example 16: Antibodies, which fully supports Applicant position.

> "Considering that the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind antigen X were implicitly disclosed as a result of the isolation of antigen X."

Again, the Examiner's position is in agreement with said Guidelines provided in Example 16. However, Applicants fail to indicate that in Example 16, the specification contemplates but does not teach in an example antibodies with specifically bind to antigen X (i.e., written support for the claimed antibody which is capable of binding to antigen X). In the same manner, Applicants' declaration fails to contemplate the claimed antibodies to the antigen. Again, a possession of a fully characterized antigen cannot be extrapolated to claims to an antibody to the antigen.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 18, 2007

Maher Haddad

Maher Haddad, Ph.D.
Primary Examiner
Technology Center 1600